

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA  
CLARKSBURG DIVISION**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

Civil Action No. 1:22-cv-00061-TSK

MYLAN PHARMACEUTICALS INC.,

Defendant.

**STIPULATED PROTECTIVE ORDER**

Pursuant to Northern District of West Virginia Local Rule 26.05, and upon agreement of the Parties for an order pursuant to Fed. R. Civ. P. 26(c), Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron”) and Defendant Mylan Pharmaceuticals Inc. (“Mylan”) (each a “Party” and collectively the “Parties”), hereby stipulate and the Court orders as follows:

**I. Definitions.**

1. As used in this Protective Order, these terms have the following meanings:
  - (a) “Patents-in-Suit” refers to United States Patents that Regeneron has claimed Mylan infringes as set forth in the Complaint filed on August 2, 2022 or any Amended Complaint that Regeneron files once it becomes the operative pleading in this Action;
  - (b) “Action” means the case captioned *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 1:22-cv-00061-TSK, which is currently pending in the Northern District of West Virginia;

- (c) “Affiliate” means any Third Party that, directly or indirectly, through one or more intermediaries controls, or is controlled by, or is under common control with, a Party to this Action;
- (d) “CONFIDENTIAL” means information that constitutes, contains, reveals, or reflects trade secrets or other confidential research, development, business, or commercial information within the meaning of Fed. R. Civ. P. 26(c)(1)(G), including but not limited to: scientific and technical information; financial (including pricing and sales information), budgeting and/or accounting information; information about existing and potential customers; marketing and other business strategies, decisions or negotiations; employee compensation, evaluation and other employment information; business plans; manufacturing information; licensing agreements; regulatory information (including non-public correspondence with the United States and foreign patent offices and regulatory agencies); and information that concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization; and any other information that is protected from disclosure by the laws of the United States or another country; and includes such confidential and proprietary information about a Third Party, including parents, subsidiaries, and/or other Affiliates; and any other information, including “Personal Data” as

defined below, the disclosure of which would harm the competitive position of the Producing Party if the information becomes known to a person or party other than the Producing Party other than as permitted hereunder;

- (e) “Designated In-house Counsel” means an attorney designated in accordance with Paragraph 6(i);
- (f) “Designating Party” is a Party or Third Party that designates information or items that it produces in Disclosures as “CONFIDENTIAL” or as “OUTSIDE COUNSEL’S EYES ONLY”;
- (g) “Disclosure(s)” means all documents; written discovery requests and responses; deposition transcripts; correspondence between the Parties; pleadings; exhibits; documents and things made available for inspection; expert testimony and reports; biological materials produced by a Party or Third Party in this Action including, but not limited to, any physical samples of cells, polynucleotides, or proteins; all other discovery taken pursuant to the Federal Rules of Civil Procedure, including Third Party discovery pursuant to Federal Rule of Civil Procedure 45; and tangible items and any other information produced or disclosed between the Parties in connection with this Action, including the pre-suit exchanges made pursuant to 42 U.S.C. § 262(l). For the sake of clarity, the production of biological samples shall be governed by the terms set forth in Paragraph 31;
- (h) “Document(s)” means all materials within the scope of Federal Rule of Civil Procedure 34(a);

- (i) “Expert” is a person with specialized knowledge or experience in a matter pertinent to the Action who (1) has been retained by a Party or its Outside Counsel to serve as an expert witness or as a consultant in this Action, (2) is not a current employee of a Party, (3) at the time of retention, is not anticipated to become an officer, director, or employee of a Party. Nothing in this Protective Order purports to alter the requirements for offering testimony under Federal Rule of Evidence 703, or to define the term “expert” for purposes other than those addressed in this Protective Order;
- (j) “In-House Counsel” means an in-house attorney who is an employee of a Party to this Action or a Party’s Affiliate;
- (k) “Third Party” is any natural person, partnership, corporation, association, or other legal entity not named as a Party to this Action;
- (l) “Outside Counsel” means the external lawyers retained by the Parties to litigate this Action and who have appeared in this Action or are acting at the direction of a lawyer who has appeared in this Action, including, but not limited to, outside attorneys admitted *pro hac vice* in this Action and paralegals, assistants and other employees of the respective law firms of Outside Counsel;
- (m) “OUTSIDE COUNSEL’S EYES ONLY” means any Disclosure that contains highly sensitive information relevant to the Designating Party’s current or prospective products, scientific or technical information, business information of current or prospective significance and for which production on a confidential basis, even to In-house Counsel, would create a substantial

risk of serious harm to the Designating Party that could not be avoided by less restrictive means.

- (n) “Party” means any party to this Action, including all of its officers, directors, employees;
- (o) “Personal Data” means any information that a Party believes in good faith to be subject to data protection laws or other privacy obligations. In particular, such data protection laws include the European Union General Data Protection Regulation (“GDPR”). “Personal Data” shall mean all information relating to an identified or (directly or indirectly) identifiable person (“Data Subject”) originating from or processed in, *inter alia*, the European Union/European Economic Area. “Personal Data” includes but is not limited to the Data Subject's name, location data (such as an address or a phone number) or online identifiers (such as email or IP addresses). All of the provisions in the Protective Order applicable to CONFIDENTIAL information will apply equally to Personal Data;
- (p) “Producing Party” is any Party or Third Party that produces or provides a Disclosure;
- (q) “Protected Material” is any Disclosure that is designated as “CONFIDENTIAL” or “OUTSIDE COUNSEL’S EYES ONLY”;
- (r) “Prosecution” means any participation in and/or contribution to drafting, amending, or modifying of patent claims in domestic and/or foreign patent office correspondence or fee payments, including during an *inter partes* review (“IPR”), post grant review (“PGR”), or any other proceeding before

a domestic and/or foreign agency, or advising a Party or other entity regarding the drafting, amending, or modifying of that Party's or other entity's patent claims. For the sake of clarity, "Prosecution" does not include participation in a challenge or in defense of a patent before a domestic or foreign agency (including but not limited to participation in *inter partes* review proceedings, post grant review proceedings, an International Trade Commission proceeding, *inter partes* reexamination, *ex parte* reexamination, reissue, certificates of correction, opposition at the European Patent Office, or other post-grant review proceedings), provided, however, that such participation does not involve, directly or indirectly, the drafting, amending, or modifying of patent claim(s);

- (s) "Protective Order" means this Stipulated Protective Order;
- (t) "Receiving Party" is any Party or Third Party receiving a Disclosure;
- (u) "Third Party" means a person or entity that is not a Party; and
- (v) "Written Assurance" means an executed document in the form attached as Exhibits A or B.

## **II. Scope.**

2. The protections conferred by this Stipulation and Order cover not only Protected Material (as defined above), but also (1) any information copied or extracted from Protected Material; (2) all copies, excerpts, summaries, or compilations of Protected Material; and (3) any testimony, conversations, or presentations by Parties or their counsel that might reveal Protected Material. However, the protections conferred by this Stipulation and Order do not cover the following information: (a) any information that is in the public domain at the time of disclosure to a Receiving Party or becomes part of the public domain after its disclosure to a Receiving Party as

a result of publication not involving a violation of this Protective Order, including becoming part of the public record through trial or otherwise; and (b) any information known to the Receiving Party prior to the disclosure or obtained by the Receiving Party after the disclosure from a source who obtained the information lawfully and under no obligation of confidentiality to the Designating Party. The Parties shall meet and confer regarding the use of Protected Material at trial, which may be governed by a separate agreement or order.

**III. Access to CONFIDENTIAL and OUTSIDE COUNSEL'S EYES ONLY Disclosures.**

3. A Producing Party may designate as "CONFIDENTIAL" or "OUTSIDE COUNSEL'S EYES ONLY" any Disclosure being furnished to any Party in connection with this Action, including any appeal(s) therefrom or any remands thereto, in accordance with this Protective Order.

4. Subject to Paragraphs 2 and 10, no person receiving such CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY Disclosures shall, directly or indirectly, disclose or communicate in any way the contents of the Disclosure(s) to any person other than those qualified pursuant to this Stipulated Protective Order.

5. All Protected Material shall be used solely for the current Action, including any appeal(s) therefrom or any remands thereto. The Parties reserve the right to, upon a showing of good cause, seek a modification of this provision from the Court if a Party believes that material produced in this case is relevant to evidence of patent infringement, non-infringement, invalidity and/or unenforceability in another country or jurisdiction. Protected Material may not be used under any circumstances for Prosecution of any patent application, for patent licensing or for any other purpose, including without limitation for any research, development, commercial, marketing, regulatory, or other competitive purpose. All persons receiving Protected Material are expressly prohibited from using or disclosing such information in connection with any practice before or

communication with the United States Patent and Trademark Office, the United States Food and Drug Administration, the United States Pharmacopoeia, or their counterpart organizations in any foreign jurisdiction. Nothing in this Protective Order shall restrict any Party's counsel from rendering advice to its clients with respect to this Action that is generally informed by Protected Material, provided, however, that in rendering such advice, counsel shall not disclose any other Party's Protected Material other than in a manner provided for in this Order.

6. Unless otherwise directed by the Court or authorized in writing by the Producing Party, all CONFIDENTIAL Disclosures may be disclosed by the Receiving Party only to the following Qualified Persons:

- (a) the Court, its officers, and any members of its staff to whom it is necessary to disclose CONFIDENTIAL information contained in CONFIDENTIAL Disclosures for the purpose of assisting the Court in this Action, and stenographic employees, court reporters and typists for the sole purpose of recording or transcribing testimony, documents, or information relating to this Action;
- (b) the Parties' Outside Counsel of record in this Action and the paralegals, assistants and other employees of the respective law firms of Outside Counsel of record in this Action to the extent such persons' duties and responsibilities require access to CONFIDENTIAL Disclosures and provided that such Outside Counsel has no current involvement and will not have involvement in any of the following activities: (1) Prosecution of any domestic or foreign patent or patent application claiming priority to the Patents-in-Suit or any related domestic or foreign patents or patent

applications, or any other domestic or foreign patent or patent application relating to aflibercept and/or covering any aflibercept subject matter disclosed in a Patent-in-Suit; (2) competitive decision making responsibilities for the sales and marketing of aflibercept; and (3) competitive decision making responsibilities for research and/or development and/or manufacturing of any aflibercept subject matter disclosed in a Patent-in-Suit; or (4) responsibility for petitioning the Food and Drug Administration (“FDA”), the United States Pharmacopoeia, or any similar foreign or domestic agency concerning aflibercept or any aflibercept subject matter disclosed in a Patent-in-Suit. This Order imposes such a Bar effective upon its entry by this Court and shall end one (1) year after final termination of this Action.

- (c) litigation support consultants (including translators, e-discovery, trial graphics, jury focus group consultants, mock jurors), outside copying services, and temporary/contract attorneys retained by Outside Counsel in this Action identified in Paragraph 6(b) with whom such Outside Counsel work in connection with this Action to the extent such persons have expressly agreed to maintain the confidentiality of their work and the CONFIDENTIAL Disclosures they receive, and provided that such personnel are not engaged in the research, development, manufacture, registration, or sale of pharmaceutical products that may be related to the subject matter of the Patents-in-Suit;
- (d) prior authors or recipients of the CONFIDENTIAL Disclosure;

- (e) qualified persons taking testimony involving such documents or information and necessary stenographic and clerical personnel thereof;
- (f) witnesses designated pursuant to Fed. R. Civ. P. 30(b)(6) may be shown CONFIDENTIAL Disclosures designated as CONFIDENTIAL by the Party for which they are testifying;
- (g) others to whom the Producing Party consents;
- (h) Experts of the Receiving Party to whom disclosure is reasonably necessary for this litigation, and who have signed a Written Assurance (attached as Exhibit A), and to whom the opposing party does not object within five (5) business days of receiving written notice to Outside Counsel of the Producing Party of an intent by the opposing party to share CONFIDENTIAL Disclosures with that Expert. Written notice under this sub-paragraph shall include the name and address of the person to whom disclosure is to be made, a current resume or curriculum vitae, a copy of the signed Written Assurance (Exhibit A), and a list of cases in which he or she has testified as an expert at trial or deposition within the last four (4) years. Any such objection must be set forth in writing and detail the grounds on which such objection is based and be made in good faith. A Party that receives a timely written objection must promptly meet and confer with the objecting Party in person or through telephonic means to attempt to resolve the matter. If the Parties are unable to reach agreement regarding such disclosure, the objecting Party may apply to the Court for a protective order or other appropriate relief no later than ten (10) days (as calculated by

Federal Rule of Civil Procedure 6) of the original written notice, and no disclosure of CONFIDENTIAL information may be made to the Expert unless and until the Motion is resolved in favor of the Receiving Party or the objection is withdrawn. New written notice does not need to be provided for Experts already identified and not objected to pursuant to the Parties' January 2022 Confidentiality Agreement, although such Experts must sign a Written Assurance and provide it the adverse Party before a Party makes further CONFIDENTIAL Disclosures to such Experts;

- (i) for each Party, up to three Designated In-house Counsel, who, because of their duties and responsibilities, require access to CONFIDENTIAL Disclosures, provided such Designated In-house Counsel have no current involvement and will not have involvement in any of the following activities: (1) Prosecution of any domestic or foreign patent or patent application claiming priority to the Patents-in-Suit or any related domestic or foreign patents or patent applications, or any other domestic or foreign patent or patent application relating to aflibercept and/or covering any aflibercept subject matter disclosed in a Patent-in-Suit; (2) competitive decision making responsibilities for the sales and marketing of aflibercept or other drugs used for ophthalmic indications; (3) competitive decision making responsibilities for the research and/or development and/or manufacturing of aflibercept or any other drugs used for ophthalmic indications; or (4) responsibility for petitioning the Food and Drug Administration ("FDA"), the United States Pharmacopoeia, or any similar

foreign or domestic agency concerning afibercept or any afibercept subject matter disclosed in a Patent-in-Suit. This Order imposes such a Bar effective upon its entry by this Court and shall end one (1) year after final termination of this Action. Designated In-house Counsel are to be designated according to the following procedure: During the pendency of this Action, a Party that seeks to designate a Designated In-house Counsel or designate a replacement Designated In-house Counsel with a new designee, must first make a written request by execution of the acknowledgment in the form attached as Exhibit B to the other Party that, among other things, (1) sets forth the full name of the Designated In-house Counsel, (2) identifies the Designated In-house Counsel's current employer, job title and job description, and (3) affirms that the Designated In-house Counsel is not involved in any of the prohibited activities set forth in this Paragraph. A Party that makes a request to designate or replace a Designated In-house Counsel and provides an executed and completed Exhibit B to the other Party's Outside Counsel may disclose CONFIDENTIAL information to the newly Designated In-house Counsel after ten (10) days of delivering the executed Exhibit B (as calculated by Federal Rule of Civil Procedure 6), unless within that ten (10) day period, the Party receives a written objection from the objecting Party. Any such objection must set forth in detail the grounds on which such objection is based and be made in good faith. A Party that receives a timely written objection must meet and confer with the objecting Party in person or through telephonic means to attempt to resolve

the matter. Following the meet and confer, the objecting Party may apply to the Court for a protective order or other appropriate relief no later than fifteen (15) days (as calculated by Federal Rule of Civil Procedure 6) after receipt of the executed acknowledgment in the form attached as Exhibit B; and

- (j) any paralegal, secretarial and clerical employee of each Party who works regularly with and reports directly or indirectly to a Designated In-house Counsel.

7. Unless otherwise directed by the Court or authorized in writing by the Producing Party, all OUTSIDE COUNSEL'S EYES ONLY Disclosures may be disclosed by the Receiving Party only to the Qualified Persons identified in Subparagraphs (a)-(h) of Paragraph 6, save that in each instance in which those Subparagraphs refer to CONFIDENTIAL Disclosures, those Subparagraphs shall be construed, solely for purposes of this Paragraph 7, as referring to OUTSIDE COUNSEL'S EYES ONLY Disclosures.

8. It is expressly understood that the number or identity of such Qualified Persons, as described in Paragraph 6, may be modified by unanimous agreement of the Parties to the Action and any Third Party(ies) that have produced Disclosures in the Action without leave of Court, or upon a showing, subject to the approval of the Court, by any Party or Third Party that such modification is necessary.

9. Nothing in this Order shall bar or otherwise restrict any attorney from rendering advice to a Party-client or, in the course thereof, relying upon his or her knowledge of Protected Material; provided, however, that in rendering such advice, the attorney shall not disclose any Protected Material information other than in a manner provided for in this Order.

10. Nothing contained in this Order shall preclude a Party from using its own Protected Material in any manner.

**IV. Designation of Disclosures.**

11. All Disclosures to be produced in tangible form that the Producing Party wishes to designate as CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY must, prior to production to the Receiving Party, be labeled on each page by the Producing Party with the legend **CONFIDENTIAL** or **OUTSIDE COUNSEL'S EYES ONLY** (or similar legend), respectively. Anything that cannot be so marked on its face shall be marked by placing the appropriate legend on a container or package in which the thing is produced or on a tag attached thereto. Each page of each document produced in discovery shall, to the extent practicable, bear a prefix identifying the Producing Party and a unique identifying number. Likewise, each discrete unit of each tangible item produced in discovery shall, to the extent practicable, also bear a prefix identifying the Producing Party and a unique identifying number.

12. Any Disclosure provided for inspection in this Action is to be treated as "OUTSIDE COUNSEL'S EYES ONLY" pending the copying and delivery of any copies of the same by the Producing Party to the Receiving Party. After copies are delivered to the Receiving Party, the information in such documents or things will be treated consistent with any legend produced on each document or thing. If no copies of Disclosures are requested in connection with an inspection, or if the Receiving Party memorializes the Disclosures during the inspection in some other fashion (e.g., notes, photographs, drawings), the Disclosures shall be treated as "OUTSIDE COUNSEL'S EYES ONLY" for seven (7) calendar days following the inspection, by which time the Producing Party must provide a written notice designating the Disclosures in the inspection as CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY, as appropriate. Inspection of documents or things by any party shall be conducted by Outside Counsel and/or Experts.

13. After the Protective Order is entered by the Court, a copy of the Protective Order shall be served along with any Third-Party subpoena or other request for Disclosure to a Third Party served or sent in connection with this Action. For a period of fourteen (14) days from the date of the production of any Disclosures in response to a Third-Party subpoena or request or after the receipt of a final transcript of a deposition pursuant to such subpoena or request, the Documents and testimony shall be treated as OUTSIDE COUNSEL'S EYES ONLY. During that 14-day period, the Disclosing Party may designate such Documents and testimony as CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY, as appropriate.

14. Testimony from any depositions or portions of any depositions taken in this Action may be designated as CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY. Confidentiality designations for depositions shall be made either on the record or by written notice to the other Party within 10 days of receipt of the final transcript. Unless otherwise agreed, depositions shall be treated as OUTSIDE COUNSEL'S EYES ONLY during the 10-day period following receipt of the transcript. A deponent may review the transcript of his or her deposition at any time. The deposition of any witness (or any portion of such deposition) that involves the disclosure of Protected Material shall be taken only in the presence of persons who are qualified to have access to such Protected Material pursuant to this Order. Persons other than the witness, the court reporter, the persons qualified to have access to such Protected Material information pursuant to this Order, and counsel for the witness (if a Third Party witness) must not be present during any portion of a deposition that involves the disclosure of Protected Material. The failure of individuals other than those specified in the previous sentence to leave the deposition room during any portion of the deposition which inquires into matters deemed CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY by the Designating Party shall constitute justification for

counsel to instruct the witness that he or she shall not answer the question(s) posed. However, the Parties (and/or Third Party, if applicable) will work to structure depositions in a way that minimizes disruption due to the use of any Protected Material that would require certain individuals to leave the deposition room as noted above.

15. This Order shall not prevent counsel from examining a witness in a good-faith effort to determine whether he or she authored, received, or previously had access to or knowledge of CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY information.

**V. Inadvertent Production/Use of CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY Information and Changes in Designation.**

16. Inadvertent production of any Disclosure without a designation as CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY will not be deemed to waive a later claim as to its confidentiality or stop the Producing Party from designating said Disclosure as CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY at a later date. If a Producing Party inadvertently does not provide a Designation to a Disclosure, or inadvertently misdesignates or mislabels a Disclosure, the Producing Party may inform the Receiving Party of the correct designation, and the Receiving Party shall treat the information in accordance with the correct designation. Promptly following such notice, the Producing Party shall provide properly designated documents or tangible items, if applicable. Upon receipt of such notice, the Receiving Party shall (i) take reasonable steps to notify any persons known to have possession of any material with the original designation of the effect of such a change in designation under this Order, (ii) promptly retrieve all copies and transcriptions of such originally designated material from any persons known to have possession of any such originally designated material who are not Qualified Persons under Paragraph 6 above to the extent practicable, and (iii) substitute properly designated copies for those previously received.

17. Should any material labeled as CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY information be disclosed by a Receiving Party to any person not authorized to have access to such information under this Order, the Receiving Party shall:

- (a) use its best efforts to obtain the prompt return of any such Protected Material and to bind such person to the terms of this Order;
- (b) within three (3) business days of the discovery of such disclosure, inform such person of the provisions of this Order and identify such person to the Producing Party; and
- (c) request such person to sign a Written Assurance in the form of Exhibit A attached hereto. If executed, the Written Assurance shall be served upon counsel of record for the Producing Party within three (3) business days of its receipt by the Receiving Party.

This Paragraph shall not prevent the Producing Party from applying to the Court for further relief.

**VI. Use of CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY Information in Filings.**

18. If the CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY information of a Producing Party is to be filed with this Court in connection with any proceeding in this Action, it shall be filed under seal in accordance with the provisions of Northern District of West Virginia Local Rule 26.05(b) or such other Order as may be made by the Court. All such documents so filed shall be released from confidential treatment only upon further order of the Court.

**VII. Challenging Designation of CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY Information.**

19. A Party may receive information designated pursuant to this Order without prejudice to its ability to later challenge the designation. A Party may challenge Disclosures on the ground that they have not been properly designated under the terms of this Order. Prior to bringing

such a challenge, however, the Receiving Party shall first request in writing that the Producing Party change or remove its confidentiality designation, and the Parties will thereupon confer as to the status of the subject information disclosed within the context of this Order. If the Parties are unable to agree upon the status of the information designated as CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY within ten (10) business days from the date of notification of such disagreement, any Party may, at any time prior to trial, present the dispute to the Court for a ruling on the matter, with the Producing Party asserting the claim of confidentiality having the burden of proof. All Disclosures designated CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY shall be treated in accordance with the designation unless and until the Court orders otherwise, or the Designating Party consents.

**VIII. Inadvertent Production/Use of Privileged Information.**

20. A Producing Party may produce a redacted version of information, documents, or tangible things that counsel contends contains information that is protected from disclosure by the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity, identifying where the privileged or immune material was redacted with the designation "REDACTED" and appropriately claiming privilege over the material pursuant to Federal Rule of Civil Procedure 26(b)(5).

21. If a Producing Party inadvertently or mistakenly produces information, documents or tangible items in this Action that should have been withheld subject to a claim of attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity, such inadvertent or mistaken production shall not prejudice or otherwise constitute a waiver of any claim of such privilege or immunity, provided that such production was inadvertent or mistaken and the Producing Party provides written notice to each Receiving Party of the inadvertent or mistaken production. Upon receipt of such written request, the Receiving Party will promptly

notify those individuals with access to the document or documents and refrain from further review of the document or documents, other than as necessary to effectuate the return or destruction of such document or documents described in this Paragraph. Within three (3) business days of receiving a written request to do so from the Producing Party, the Receiving Party shall return to the Producing Party or destroy any documents or tangible items that the Producing Party represents are covered by a claim of privilege or immunity and which were inadvertently or mistakenly produced. If the Receiving Party intends to challenge the claim of privilege or inadvertence it may, upon written notice to the Producing Party, ask the Producing Party to identify on its existing or supplemental privilege log the specific document or documents that were inadvertently or mistakenly produced. The Producing Party shall preserve copies of all returned documents and tangible items for further disposition. Nothing in this Order shall preclude the Receiving Party from making a motion to compel production of the returned information.

22. Pursuant to Federal Rule of Evidence 502(d), the production of a privileged or work-product-protected document is not a waiver of privilege or protection from discovery in this case or in any other federal or state proceeding. For example, the mere production of privilege or work-product-protected documents in this case as part of a mass production is not itself a waiver in this case or any other federal or state proceeding.

23. This Order shall not prevent any party from applying to the Court for further or additional protective orders.

24. Even after final disposition of this Action, the confidentiality obligations imposed by this Order shall remain in effect until a Designating Party agrees otherwise in writing or a court order otherwise directs. “Final Disposition” shall be deemed to be the later of (1) dismissal of all claims, counterclaims, and defenses in this action, with or without prejudice; and (2) final

judgment herein after the completion and exhaustion of all appeals, rehearings, remands, trials, or reviews of this action, including the expiration of any time limits for filing any motions or applications for extension of time pursuant to applicable law.

**IX. Disposition of CONFIDENTIAL and OUTSIDE COUNSEL'S EYES ONLY Disclosures upon Conclusion of this Action.**

25. Within sixty (60) calendar days of the Final Disposition of this Action (including any appeals or the expiration of the period during which an appeal may be sought), each Party, including its counsel, agents, and experts, shall either destroy or return to the opposing party all Protected Material, although such efforts need not encompass a review and purge of backup tapes. Any material that continues to reside on backup tapes shall remain subject to the other terms of this Protective Order. Each Party shall provide a certification as to such return or destruction within the 60- day period. Outside Counsel may retain, however, all documents and things that contain or reflect their attorney work product, all correspondence, all pleadings, all deposition transcripts, all expert reports, all deposition, hearing and trial exhibits, and all court-filed documents even though they contain Protected Material information, but such retained work product and documents shall remain subject to the terms of this Order. Accordingly, within sixty (60) days of the Final Disposition of this Action, no one other than Outside Counsel shall retain any Documents incorporating Protected Material except as expressly provided for in this Paragraph.

26. Before the sixty (60) day period specified in Paragraph 25 has elapsed, the Parties shall attempt to agree in good faith as to the date that they believe is the date that is sixty (60) days after Final Disposition.

27. The procedures of Paragraph 25 likewise shall apply to the handling of Protected Material by a Receiving Party who ceases to be a Party to this Action, so that such a Party is not

entitled to retain Protected Material through Final Disposition of the Action if it ceases to be a Party prior to that date. Such a Party shall complete the requirements of Paragraph 25 within sixty (60) days following an order dismissing it from the case.

28. Within sixty (60) days following the Final Disposition of this Action, the Parties may remove any CONFIDENTIAL documents or materials from the office of the Clerk of Court. Following that 60-day period, the Clerk of Court may destroy all other materials at the Court's discretion.

**X. Produced Material Sought or Ordered to Be Produced in Another Proceeding or by Operation of Law**

29. If a Party is served with a subpoena, order, or other form of process issued by any court or any arbitral, administrative or legislative body, or are otherwise requested in discovery in other litigation, or by any other operation of law, that requires or compels disclosure of any information or items designated in this Action as "CONFIDENTIAL," that Party must:

- (a) promptly notify in writing the Designating Party. Such notification shall include a copy of the subpoena or order;
- (b) promptly notify in writing the party who caused the subpoena or order to issue that some or all of the material covered by the subpoena or order is subject to this Protective Order. Such notification shall include a copy of this Protective Order; and
- (c) cooperate with respect to all reasonable procedures to protect the confidentiality of the information sought to be pursued by the Designating Party whose Protected Material may be affected.

30. If the Designating Party takes steps to prevent disclosure of such documents within seven (7) business days of the date written notice is given, the Party served with the subpoena,

order, or other form of process shall not produce any information designated in this action as CONFIDENTIAL or OUTSIDE COUNSEL'S EYES ONLY before a determination by a court of appropriate jurisdiction unless the Party has obtained the Designating Party's permission. The Designating Party shall bear the burden and expense of seeking protection in that court of its confidential material – and nothing in these provisions should be construed as authorizing or encouraging a Receiving Party in this action to disobey a lawful directive from another court.

**XI. Miscellaneous Provisions.**

31. In the event that any party produces biological materials including, but not limited to, any physical samples of cells, polynucleotides, or proteins, such material shall be designated OUTSIDE COUNSEL'S EYES ONLY and treated accordingly, provided, however, that sufficient information derived from reports and analysis of such material may be shared with the Parties' Designated In-House Counsel to allow outside counsel to discuss with such personnel Mylan's infringement of Regeneron's patents.

32. This Order shall apply to all documents, information, and material produced pursuant to the Parties' Section 262(l) Confidentiality Agreement entered in January 2022. Within fourteen (14) days of the date of this Order, the documents, information, and material produced pursuant to that Confidentiality Agreement shall be produced in this matter with confidentiality designations made in accordance with this Order. To the extent a Party previously produced material in a format that would not permit an opposing Party to download and/or print the material, it shall be produced in the timeframe set forth in this Paragraph in a manner that permits downloading and printing.

33. By written agreement of the Parties, or upon motion and order of the Court, the terms of this Order may be amended or modified as to Protected Material produced by the Parties. By written agreement of the Parties together with any Third Party who has produced Protected

Material pursuant to this Order, or upon motion and order of the Court, the terms of this Order may be amended or modified as to Protected Material produced by the Third Party whose Protected Material is the subject of any such agreement or Order.

34. By stipulating to the entry of this Protective Order, no Party waives any right it otherwise would have to object to disclosing or producing any information or item on any ground not addressed in this Protective Order. Similarly, no Party waives any right to object on any ground to use in evidence of any of the material covered by this Protective Order.

35. This Court will retain jurisdiction over all persons subject to this Order to the extent necessary to enforce any obligations arising hereunder or to impose sanctions for any contempt thereof.

36. Nothing in this Order abridges the right of any person to seek its modification by the Court in the future.

**ORDER**

Based on the foregoing stipulation, and good cause appearing therefore, **IT IS SO ORDERED** this 2nd day of November, 2022.

*Tom S. Kline*

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United States District Judge

**EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA  
CLARKSBURG DIVISION**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

Civil Action No. 1:22-cv-00061-TSK

MYLAN PHARMACEUTICALS INC.,

Defendant.

**WRITTEN ASSURANCE**

I, \_\_\_\_\_, declare that:

1. I am currently employed by \_\_\_\_\_ located at \_\_\_\_\_ and my current job title is \_\_\_\_\_.

2. I have read and believe I understand the terms of the Protective Order dated \_\_\_\_\_, 2022, filed in Civil Action No. 1:22-cv-00061-TSK, pending in the United States District Court for the Northern District of West Virginia. I agree to comply with and be bound by the provisions of the Protective Order. I understand that any violation of the Protective Order may subject me to sanctions by the Court and that any or all of the Parties or Third Parties that designate information pursuant to the Protective Order may assert other remedies against me.

3. I shall not divulge any CONFIDENTIAL information or documents pursuant to the Protective Order, including copies of the documents or any information contained in the CONFIDENTIAL documents, to any person other than those authorized to receive the information or documents under the Protective Order. I shall not copy or use such documents except for the purposes of this Action and pursuant to the terms of the Protective Order. I will take reasonable

steps to restrict access to any CONFIDENTIAL information to only those persons authorized by the Protective Order to have such access.

4. As soon as practical, but no later than sixty (60) days after Final Disposition of this Action (including any appeals or the expiration of the period during which an appeal may be sought), I shall comply with Paragraph 25 of this Protective Order.

5. I submit myself to the jurisdiction of the United States District Court for the Northern District of West Virginia for the purpose of enforcing or otherwise providing relief relating to the Protective Order.

Date: \_\_\_\_\_

\_\_\_\_\_ (Signature)

**E HIBIT B**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA  
CLARKSBURG DIVISION**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

Civil Action No. 1:22-cv-00061-TSK

MYLAN PHARMACEUTICALS INC.,

Defendant.

**DESIGNATED IN HOUSE COUNSEL WRITTEN ASSURANCE**

I, \_\_\_\_\_, declare that:

1. I am currently employed by \_\_\_\_\_ located at \_\_\_\_\_

and my current job title is \_\_\_\_\_.

2. My current job description, including a brief summary of my duties and responsibilities, is as follows:

3. I have read and believe I understand the terms of the Protective Order dated \_\_\_\_\_, 2022, filed in Civil Action No. 1:22-cv-00061-TSK, pending in the

United States District Court for the Northern District of West Virginia. I agree to comply with and be bound by the provisions of the Protective Order. I understand that any violation of the Protective Order may subject me to sanctions by the Court and that any or all of the Parties or Third Parties that designate information pursuant to the Protective Order may assert other remedies against me.

4. I affirm that I will not use any CONFIDENTIAL Disclosures of another Party for the prohibited activities set forth in Paragraph 6(i) of the Protective Order.

5. I shall not divulge any CONFIDENTIAL information or documents pursuant to the Protective Order, including copies of the documents or any information contained in the CONFIDENTIAL documents, to any person other than those authorized to receive the information or documents under the Protective Order. I shall not copy or use such documents except for the purposes of this Action and pursuant to the terms of the Protective Order. I will take reasonable steps to restrict access to any CONFIDENTIAL information to only those persons authorized by the Protective Order to have such access.

6. As soon as practical, but no later than sixty (60) days after Final Disposition of this Action (including any appeals or the expiration of the period during which an appeal may be sought), I shall comply with Paragraph 25 of this Protective Order.

7. I submit myself to the jurisdiction of the United States District Court for the Northern District of West Virginia for the purpose of enforcing or otherwise providing relief relating to the Protective Order.

Date:

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(Signature)